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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,080	02/27/2002	David H. Mack	018501-000840US	2006

20350 7590 10/22/2004

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EXAMINER

MARTINELL, JAMES

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 10/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	10/087,080	Applicant(s)	MACK ET AL.
Examiner	James Martinell	Art Unit	1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 06 August 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-4 and 6-36 is/are pending in the application.
- 4a) Of the above claim(s) 8-21 and 33-36 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-4, 6, 7, and 22-32 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date: _____
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) 5) Notice of Informal Patent Application (PTO-152)
Paper No(s)/Mail Date: _____ 6) Other: _____

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Claims 8-21 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on February 20, 2004.

Newly submitted claims 33-36 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the claims are drawn to methods of measuring polypeptides and properly belong in Group III as outlined in the requirement for restriction mailed November 20, 2003.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 33-36 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

The disclosure is objected to because of the following informalities.

- (a) The amendment filed October 25, 2002 and the Sequence Listing have been received and entered. The Sequence Listing of October 25, 2002 is improper in that it does not contain a statement that no new matter is present in the new Sequence Listing. See 37 CFR §§ 1.821-1.825 (especially § 1.821(g)) and MPEP 2420-2430 (especially 2428)).

Appropriate correction is required.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4, 6, 7, and 22-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague, indefinite, and incomplete.

- (a) The recitation of "selectively hybridizes" (claim 1) is vague, indefinite, and incomplete because the term is a relative one without a frame of reference. This rejection is repeated for reasons already of record (*e.g.*, Office action mailed May

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6, 2004, page 3, item (a)). Applicants' argument (response filed August 6, 2004, page 12) is not convincing because applicants do not address the issue of the presence of other sequences within the reaction mix that can hybridize with SEQ ID NO: 31.

- (b) The recitation of "selectively hybridizes to a sequence . . . at least 95% identical to SEQ ID NO: 31" (claim 1) is vague, indefinite, and incomplete because the metes and bounds of the claim are unknowable. It cannot be determined what may "selectively" hybridize to such a large number of sequences. There are no fewer than 3.3×10^{138} nucleotide sequence variations of SEQ ID NO: 31 that are 95% identical to SEQ ID NO: 31. There are 1.32×10^{36} possible sequences of 60 nucleotides length. The rest of this part of this rejection is repeated for reasons already of record (*e.g.*, Office action mailed May 6, 2004, page 3, item (b)).
- Applicants' arguments (response filed August 6, 2004, page 12) are not convincing because applicants do not address the issue of maximally stable DNA duplexes of greater than 50 base pairs (Kennell (Progr. Nucl. Acid Res. Mol. Biol. 11: 259 (1971), paragraph bridging pages 260-261). Applicants merely assert that one of ordinary [sic] skill in the art would know what the metes and bounds of the claims are without providing a reason for the conclusion.

Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for reasons already of record (*e.g.*, Office action mailed May 6, 2004, first full paragraph on page 4).

Applicants' argument (response filed August 6, 2004, page 13) is not convincing because there are no fewer than 3.3×10^{138} nucleotide sequence variations of SEQ ID NO: 31 that are 95% identical to SEQ ID NO: 31. There are 1.32×10^{36} possible sequences of 60 nucleotides length. DNA duplexes of greater

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than 50 base pairs are maximally stable (see Kennell, paragraph bridging pages 260-261). The sequences embraced by the claims that contain insertions of 60 nucleotides would hybridize specifically to DNAs that have not been described in the application.

Claims 1-4, 6, 7, and 22-32 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. This rejection is repeated for reasons already of record (*e.g.*, Office action mailed May 6, 2004, page 4). Applicants' arguments (response filed August 6, 2004, paragraph bridging pages 13-14) are not persuasive because there is no clear connection in the application between SEQ ID NO: 31 and Unigene ID Hs. 163900. Table 26 as originally filed shows SEQ ID NO: 31 is Accession No. NM_033260.1 while Table 22 shows Hs. 163900 to be Accession No. AA292998.

Claims 1-4, 6, 7, and 22-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is repeated for reasons already of record (*e.g.*, Office action mailed May 6, 2004, page 4). The discussion in the previous rejection is incorporated here.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Martinell whose telephone number is (571) 272-0719. The fax phone number for Examiner Martinell's desktop workstation is (571) 273-0719. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be e-mailed to james.martinell@uspto.gov. Since e-mail communications may not be secure, it is suggested that information in such requests be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-0722.

FAX NUMBER

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.


James Martinell, Ph.D.
Primary Examiner
Art Unit 1631

10/20/04